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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,317	12/17/2003	Timothy A. Becker	65306-0092	8901

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT PAPER NUMBER

1618

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/738,317	<b>Applicant(s)</b> BECKER ET AL.	
	<b>Examiner</b> James W. Rogers	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 are rejected under U.S.C. 102(e) as being anticipated by Kipke et al. (US 6,592,566).

Applicants arguments filed 11/10/2005 have been fully considered but they are not persuasive.

Applicant asserts that Kipke does not teach injection of the purified alginate liquid and calcium chloride solution begins or ends asynchronously.

The relevance of this assertion is unclear. Kipke states the injection of purified alginate liquid and calcium chloride may be injected in stages (col 4, lin 35-47), by definition asynchronous injection would mean the injections would not occur at the same time and the word staged could also mean the injections would not occur at the same time.

Applicant also asserts that the office action contains no discussion of how Kipke teaches or discloses the respective additional elements of dependent claims 2-16.

Again, the relevance of this is not seen. The limitations of the dependent claims 2-16 don't differ over the prior art methodologies as these claims use broad and somewhat relative terms such as "low" and "continuous and variable" which would be

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inherent in the prior arts methodology since almost any injection could be continuous for some time period and the molecular weights of the alginates are known in the prior art to be varied over a wide range.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke et al. (US 6,592,566).

Applicants arguments filed 11/10/2005 have been fully considered but they are not persuasive.

Applicant asserts that Kipke does not teach injection of the purified alginate liquid and calcium chloride solution begins or ends asynchronously. Applicant also asserts that in respect to claim 25, "Kipke does not teach or disclose at least the elements of providing an ion-permeable balloon to a targeted area in a vascular system and injecting the two components into the balloon".

The relevance of this assertion is unclear. For claims 1-24 and 26-32 the Kipke patent teaches as described above. Regarding claim 25 Kipke references the Cochrum patent (US 5,614,204), which does state that a method for obstructing blood flow is balloon occlusion.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochrum (US 5,614,204) in view of Kipke et al. (US 6,592,566).

Applicants arguments filed 11/10/2005 have been fully considered but they are not persuasive.

Applicant asserts that in the office action Cochrum does not teach controlled and simultaneous administration of vascular occlusive agents comprising alginate and calcium chloride and neither Cochrum or Kipke discloses the novel feature of injecting the calcium chloride and alginate solutions asynchronously. The applicant further states that Cochrum and Kipke do not teach all the elements of independent claim 25.

The relevance of this assertion is unclear. Since the Cochrum patent is used in a 103(a) rejection in view of Kipke that single document does not have to contain all of the limitations set forth in all the claims. Cochrum does disclose in the specification that a method for obstructing blood flow is balloon occlusion. The Kipke patent teaches as described above.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke et al. (US 6,592,566) in view of Stabler (Biomaterials 22 (2001) 1301).

The Kipke patent teaches as described above. Kipke does not teach an alginate with a molecular weight within the range provided by the applicants.

Stabler teaches the effects of alginate composition on encapsulated  $\beta$ TC3 cells, one of the alginates had a molecular weight within the range provided by the applicants, See page 1302 Table 1. Stabler does not teach asynchronous injection of the alginate and calcium chloride solution.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Kipke teaches injection of purified alginate and calcium chloride liquids in stages while Stabler teaches an alginate with a MW within the range cited by the applicants. One would have been motivated to make an asynchronous injection of the alginate of specified molecular weight and calcium chloride solution in order to form an endovascular occlusion.

### ***Conclusion***

No claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 271-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHAEL HARTLEY  
PRIMARY EXAMINER